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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,107	01/24/2001	Vincent P. Sandanyaka	WYTH0144-100/AM100182	4495
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Pepper Hamilton LLP/Wyeth 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183				
EXAMINER				
COVINGTON, RAYMOND K				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
05/22/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

09/769,107

**Applicant(s)**

SANDANAYAKA ET AL.

**Examiner**

Raymond Covington

**Art Unit**

1625

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14, 29-31, 33-39, 45-48 and 53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 29-31, 33-39, 45-48 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 29-31, 33-39, 45-48 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of formula IX where R<sub>4</sub> may contain a piperidine, pyrrole, pyridine, thiophene or dioxo substituent it does not reasonably provide enablement for the broader scope of alphanumerics Y, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>5</sub> in claims dependent thereon. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Specification provides no guidance as to what other rings, for example, might be suitable and there is no basis in the prior art directed to similar compounds having the same activity as herein.

The Wands factors are again applied as set forth in the previous office action. Applicants' comments have been noted and considered but are not deemed persuasive of patentability.

There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and further would not be produced by the same process. Note *In re Surrey* 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

There is insufficient disclosure of starting materials that would place such a diverse genus of compounds in possession of the public in the event of a patent grant.

This is particularly true where large groups such as heteroaryl may sterically hinder or may prevent the making of the starting materials, intermediates or final products.

Though clearly one of ordinary skill in the art could identify much of what is within the scope of Y, R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, and R<sub>5</sub> the delineation between what is and what is not claimed has not been circumscribed. That is, all of what is claimed is not identifiable. Heteroaryl and cycloheteroalkyl groups are also an optional substituent on a Heteroaryl and cycloheteroalkyl groups. The specification only provides some examples of what these terms may signify, but does not limit heterocyclic to any particular definition. For example, page 19-20 teach many “particularly preferred” examples of “heterocyclic groups,” but this section is

prefaced with “preferred,” so it is clear that applicants do not wish to be limited to only those named heterocycles. Again, where the delineation between claimed subject matter and unclaimed subject matter lies is unclear from a reading of the claims in light of the specification. More than one definition of the general term “heteroaryl” or “heterocycle” is accepted by those of ordinary skill in the art of organic chemistry. Some consider cyclic organic compounds wherein at least one carbon atom is replaced by sulfur, oxygen or nitrogen to be heterocyclic compounds, while others of ordinary skill include selenium, tellurium, boron or tin containing rings to be within the scope of the term heterocyclic as it is commonly used, and some definitions of heterocyclic do not require carbon to be present at all.

The examiner directs applicants' attention to the following three references:

On page 282 of the McGraw--Hill Dictionary of Chemical Terms(1990), the definition of “heterocyclic compound” is a compound in which the ring structure is a combination of more than one kind of atom. On page 490 of the Concise Encyclopedia Chemistry (1993), the definition of “heterocycles” is cyclic hydrocarbon compounds in which the ring consists of carbon and at least one other element, usually, N, O or S. The definition goes on to explain that the possibilities for synthesis are nearly unlimited, and that compounds wherein the heteroatoms are of elements like phosphorous, arsenic, selenium, and tellurium are being

incorporated with increasing frequency. On page 594 of Hawley's Condensed Chemical Dictionary (1993), "heterocyclic" is defined as a closed-ring structure, usually, either 5 or 6 members, in which one or more of the atoms in the ring is an element other than carbon, e.g. sulfur, nitrogen, etc. These three definitions should make it abundantly clear that there is no one specific and exact definition of the word "heterocyclic," thus when this term is present as a claim limitation, the metes and bounds of protection are not pointed out and distinctly claimed. Though the three above-cited definitions of the term have some shared aspects, chemists of ordinary skill would not necessarily agree on the full scope and meaning of the term "heterocyclic."

The numerous substituent variables and their voluminous complex meanings and their seemingly endless permutations and combinations make it virtually impossible to determine the full scope and complete meaning of the claimed subject matter. As presented, the subject matter cannot be regarded as being a clear and concise description for which protection is sought.

No claim are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres at telephone number (571) 272-0867.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. C./  
Examiner, Art Unit 1625

/Janet L. Andres/  
Supervisory Patent Examiner,  
Art Unit 1625

RKC